

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: John E. Ahern and James F. Crittenden  
SERIAL NO.: -----  
FILED: HERewith  
FOR: SYSTEMS AND METHODS FOR LOCAL DELIVERY  
OF AN AGENT  
EXAMINER: Carlos Azpuru  
ART UNIT: 1615

BOX PATENT APPLICATION  
Commissioner for Patents  
Washington, DC 20231

**PRELIMINARY AMENDMENT**

Sir:

Please amend the above-entitled application as follows:

**Specification**

Page 1, after the title, please insert the following:

**Related Application**

This application is a divisional of application Serial No. 08/993,586 filed  
December 18, 1997.

Please replace the paragraph beginning at page 4, line 22, with the following  
rewritten paragraph:

In a further embodiment, the apparatus can further include a plunger for driving a therapeutic agent from the delivery chamber. The plunger can include a ratchet assembly for allowing the delivery of discrete volumes of therapeutic agent, or a discrete number of pellets containing a therapeutic agent. Alternatively, the plunger can be provided with a threaded assembly and worm gear assembly for rotatably advancing the plunger into the delivery chamber responsive to a rotating action. Accordingly, an actuator such as a plunger disposed within the delivery chamber can act on pellets of therapeutic agents stored within the delivery chamber to force the pellets from the

delivery chamber and implant them within a tissue wall. Optionally a delivery chamber can be dimensioned to receive one or a plurality of pellets containing a therapeutic agent. The activation of the plunger or actuator can be by manipulation of a lever action handle mounted at the proximal end of the flexible body and coupled to the control mechanism. Alternatively, a rotary mechanism, optionally motorized, can be provided for rotating a threaded plunger to advance the plunger within the delivery chamber thereby forcing pellets of therapeutic agent from the chamber.

Please replace the paragraph beginning at page 10, line 23, with the following rewritten paragraph:

More specifically, the plunger 33 depicted in Fig. 2A includes a plate 38 and an actuating rod 40. The plate 38 is dimensioned to fill substantially the diameter of interior chamber 24 to provide thereby a surface that is adapted for forcing the minispheres 22 through the chamber 24 and out of port 30. The actuating rod 40 is connected to the plate 38 and provides a mechanical force to plate 38 to advance, or drive, the plate 38 distally into the chamber 24. In one embodiment, the actuating rod 40 extends through the catheter 12 and couples to the control mechanism/handle 18 at the proximal end of device 10. In this embodiment, the control mechanism/handle 18 includes a mechanism that drives the actuating rod 40 distally causing minispheres 22 to be delivered through port 30. Optionally, this embodiment can include a control mechanism/handle 18 that incorporates a ratchet assembly that drive the actuating rod 40 distally in discrete steps wherein a predetermined number of steps corresponds substantially to the diameter of one of the minispheres 22. For example, the depicted control switch 20 can be a rotatable switch that allows for manual actuation of a ratchet assembly contained within the control mechanism/handle 18. The ratchet assembly allows the physician to drive the plunger 33 distally into the chamber 24 thereby driving the minisphere 22 out of the port 30. In this way, the device 10 can allow for the discrete and sequential delivery of minispheres 22 from the delivery chamber 14.

### **Claims**

Cancel claims 1-18.

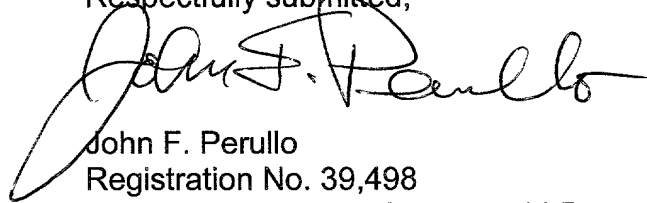
**REMARKS**

This divisional application is being filed to continue prosecution of claims 19-31 of parent application Serial No. 08/993,586. In the parent application, claims 19-31 were subject to a restriction requirement and were non-elected. Those claims are to be pursued in the present application. Claims 1-18, which were prosecuted in the parent application, are now canceled from the present application.

The amendments made to the specification herein are presented to reflect the amendments that were made during the prosecution of the parent application and to indicate that this is a divisional application. The amendments do not add new matter.

Consideration of the foregoing amendments and a favorable determination of patentability of the claims is earnestly requested.

Respectfully submitted,



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Docket No.: B0410/7282D1

Date: June 25, 2001

**VERSION WITH MARKINGS TO SHOW CHANGES MADE****In the Specification**

Page 1, after the title, the following was inserted:

**--Related Application**

This application is a divisional of application Serial No. 08/993,586 filed September 30, 1998.--

Paragraph beginning at line 22 of page 4 has been amended as follows:

In a further embodiment, the apparatus can further include a plunger for driving a therapeutic agent from the delivery chamber. The plunger can include a ratchet assembly for allowing the delivery of discrete volumes of therapeutic agent, or a ~~disereet~~ discrete number of pellets containing a therapeutic agent. Alternatively, the plunger can be provided with a threaded assembly and worm gear assembly for rotatably advancing the plunger into the delivery chamber responsive to a rotating action. Accordingly, an actuator such as a plunger disposed within the delivery chamber can act on pellets of therapeutic agents stored within the delivery chamber to force the pellets from the delivery chamber and implant them within a tissue wall. Optionally a delivery chamber can be dimensioned to receive one or a plurality of pellets containing a therapeutic agent. The activation of the plunger or actuator can be by manipulation of a lever action handle mounted at the proximal end of the flexible body and coupled to the control mechanism. Alternatively, a rotary mechanism, optionally motorized, can be provided for rotating a threaded plunger to advance the plunger within the delivery chamber thereby forcing pellets of therapeutic agent from the chamber.

Paragraph beginning at line 23 of page 10 has been amended as follows:

More specifically, the plunger 33 depicted in Fig. 2A includes a plate 38 and an actuating rod 40. The plate 38 is dimensioned to fill substantially the diameter of interior chamber 24 to provide thereby a surface that is adapted for forcing the minispheres 22 through the chamber 24 and out of port 30. The actuating rod 40 is connected to the plate 38 and provides a mechanical force to plate 30 to advance, or drive, the plate 38 distally into the chamber 24. In one embodiment, the actuating rod 40 extends through the catheter 12 and couples to the control mechanism/handle 18 at the proximal end of device 10. In this embodiment, the control mechanism/handle 18 includes a mechanism that drives the actuating rod 40 distally causing minispheres 22

to be delivered through port 30. Optionally, this embodiment can include a control mechanism/handle 18 that incorporates a ratchet assembly that drive the actuating rod 40 distally in ~~disereet~~ discrete steps wherein a predetermined number of steps corresponds substantially to the diameter of one of the minispsheres 22. For example, the depicted control switch 20 can be a rotatable switch that allows for manual actuation of a ratchet assembly contained within the control mechanism/handle 18. The ratchet assembly allows the physician to drive the plunger 33 distally into the chamber 24 thereby driving the minisphere 22 out of the port 30. In this was, the device 10 can allow for the ~~disereet~~ discrete and sequential delivery of minispheres 22 from the delivery chamber 14.

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